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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,425	02/05/2002	Norihiro Kikukawa	Q68263	4121
23373	7590	07/06/2004	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			SAUCIER, SANDRA E	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,425

Applicant(s)

KIKUKAWA ET AL.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 11–27 are pending and are considered on the merits.

Claim Rejections – 35 USC § 112

Claims 11–27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In claims 11 and 19, an insertion has been made that reads: "and wherein the freeze-dried prothrombin time measuring reagent does not contain adsorbed plasma."

Applicants have not pointed to the place in the specification or originally filed claims where this recitation is supported, and the examiner cannot locate support for this recitation. Therefore, it is considered to be new matter.

Claim Rejections – 35 USC § 102

Claims 11, 12, 14–16, 18–20, 22–27 are no longer rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 06–337267 [O] because of the insertion of new matter.

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of the above art rejection over these claims. However, removal of new matter will result in the reinstatement of the art rejections.

Claim Rejections – 35 USC § 103

Claims 11–27 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 06–337267 [O] taken with US 5,314,695 [B] or US 5,298,599 [A].

The claims are directed to a freeze-dried composition comprising a thromboplastin with an ISI of more than 1,
an amino acid selected from the specifically recited group,
wherein the reagent does not contain adsorbed plasma.

Claims 13, 17, 21 and 26 are directed to the use of recombinantly produced thromboplastin.

JP 06-337267 discloses a method of making a thromboplastin composition comprising: adding sodium glutamate to a thromboplastin solution and freeze drying (Example 3). The composition in the examples contain adsorbed plasma in the composition which is a source of some coagulation factors.

US 5,298,599 or US 5,314,695 are cited to show that recombinantly produced thromboplastin is known in the art.

The substitution of a recombinantly produced thromboplastin for the thromboplastin of the primary references would have been obvious when they were taken with US 5,298,599 [A] or US 5,298,599 [B] who teach the production and equivalency of thromboplastin from natural sources and recombinantly produced thromboplastin.

Whether or not the plasma is included in the composition appears to be an element of experimental design as JP 06-337267 generically teaches that the reagent contains at least one component selected from the group which consists of ... cow adsorption plasma etc., so that one of skill in the art, if not wishing to include plasma which is the source of factors I and V, are given the suggestion to exclude it. The patent clearly teaches that the inclusion of an amino acid, specifically exemplified is sodium glutamate, increases the reproducibility of the coagulation test as well as the signal strength of the test, see Table 1.

Response to Arguments

Applicant's arguments filed 6/9/04 have been fully considered but they are not persuasive.

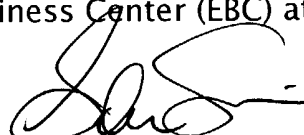
Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651